**For United Kingdom**
**Eylea® (aflibercept) 40 mg/mL solution for injection in a vial & in pre-filled syringe; Eylea® (aflibercept) 114.3 mg/mL solution for injection in a vial & (in Great Britain only) in pre-filled syringe**
**Prescribing Information** (Refer to full Summaries of Product Characteristics (SmPCs) before prescribing)

**Presentation(s): Eylea 40 mg/mL**: 1 mL solution for injection contains 40 mg aflibercept. *Vial*: One vial contains extractable volume of at least 0.1 mL, equivalent to at least 4 mg aflibercept. *Pre-filled syringe (PFS)*: One PFS contains extractable volume of at least 0.09 mL, equivalent to at least 3.6 mg aflibercept **Eylea 114.3 mg/mL**: 1 mL solution for injection contains 114.3 mg aflibercept. *Vial*: Each vial contains 30.1 mg aflibercept in 0.263 mL solution, providing a usable amount to deliver a single dose of 0.07 mL containing 8 mg aflibercept. ***In Great Britain only**, pre-filled syringe (PFS)*: Each PFS contains 21 mg aflibercept in 0.184 mL solution, providing a usable amount to deliver a single dose of 0.07 mL containing 8 mg aflibercept. **Indication(s):** Treatment in adults of neovascular (wet) age-related macular degeneration (nAMD), and visual impairment due to diabetic macular oedema (DMO).
**Posology & method of administration:** Administration by intravitreal injection only, according to medical standards and applicable guidelines by **(in Great Britain only)** a qualified healthcare professional experienced in administering intravitreal injections **OR (in Northern Ireland)** a qualified physician experienced in administering intravitreal injections. Use 30 G × ½ inch injection needle. **Eylea 40 mg/mL**: Each vial or PFS should only be used for treatment of a single eye; extraction of multiple doses may increase risk of contamination and infection. The vial or PFS contains more than the recommended dose of 2 mg. The extractable volume of the vial (0.1 mL) or PFS (0.09 mL) is not to be used in total. Expel excess volume and bubbles before injecting. Refer to SmPC for full details. **Eylea 114.3 mg/mL**: Each vial or **(in Great Britain only)** PFS should only be used for the treatment of a single eye; extraction of multiple doses from vial or **(in Great Britain only)** from a single PFS with OcuClick dosing system may increase risk of contamination and infection. The 8 mg dose requires use of Eylea 114.3 mg/mL vial or **(in Great Britain only)** PFS with OcuClick dosing system; check label to ensure correct Eylea strength. The extractable volume of the vial (0.263 mL) or total volume of the **(in Great Britain only)** PFS (0.184 mL) is not to be used in full. Expel excess volume and bubbles before injecting. Refer to SmPC for full details. ***Adults:* Eylea 40 mg/mL:** Recommended dose is 2 mg aflibercept, equivalent to 0.05 mL. For nAMD treatment is initiated with 1 injection per month for 3 consecutive doses. Treatment interval is then extended to 2 months. Based on the physician's judgement of visual and/or anatomic outcomes, treatment interval may be maintained at 2 months or further extended using a treat-and-extend (T&E) dosing regimen, where injection intervals are increased in 2- or 4-weekly increments to maintain stable visual and/or anatomic outcomes. If visual and/or anatomic outcomes deteriorate, the treatment interval should be shortened accordingly. No requirement for monitoring between injections. Based on the physician's judgement the schedule of monitoring visits may be more frequent than the injection visits. Treatment intervals greater than 4 months or shorter than 4 weeks have not been studied. For DMO, initiate treatment with 1 injection/month for 5 consecutive doses, followed by 1 injection every 2 months. Based on physician's judgement of visual and/or anatomic outcomes, maintain treatment interval at 2 months or individualise, such as with a T&E dosing regimen, usually increasing treatment intervals by 2-week increments to maintain stable visual and/or anatomic outcomes. Limited data for treatment intervals longer than 4 months. Shorten treatment interval if visual and/or anatomic outcomes deteriorate. Treatment intervals shorter than 4 weeks not studied. Monitoring schedule should be determined by treating physician. Discontinue treatment if visual and anatomic outcomes show lack of benefit. **Eylea 114.3 mg/mL:** Recommended dose is 8 mg aflibercept, equivalent to 0.07 mL solution. Posology is the same for nAMD and DMO indications: treatment is initiated with 1 injection per month for 3 consecutive doses. Injection intervals may then be extended up to every 4 months based on physician's judgement of visual and/or anatomic outcomes. Subsequently, treatment intervals may be further extended up to 5 months, such as with a treat-and-extend (T&E) dosing regimen, while maintaining stable visual and/or anatomic outcomes. If visual and/or anatomic outcomes deteriorate, treatment interval should be shortened according to physician's discretion. Shortest interval between 2 injections is 2 months in maintenance phase. Eylea at monthly doses of 8 mg has not been studied for more than 3 consecutive doses. Frequency of monitoring visits should be based on patient's status and physician's discretion. **Special populations: *Hepatic and/or renal impairment:*** No specific studies conducted. Available data do not suggest need for a dose adjustment. ***Elderly:*** Available data do not suggest need for dose adjustment. Limited experience of Eylea 40 mg/mL in those with DMO over 75 years old. ***Paediatric:* Eylea 40 mg/mL:** No data available for nAMD, DMO. **Eylea 114.3 mg/mL:** Safety and efficacy not established in paediatric population; no relevant paediatric use.

**Contraindications:** Hypersensitivity to active substance or any excipient; active or suspected ocular or periocular infection; active severe intraocular inflammation.

**Warnings & precautions:** Record name and batch number of administered product for traceability. As with other intravitreal therapies endophthalmitis, intraocular inflammation, retinal detachment, retinal tear and traumatic cataract have been reported. Aseptic injection technique essential. Patients must report symptoms of endophthalmitis or any of the above-mentioned events without delay. Monitor patients during the week following injection to permit early treatment of infection. Increases in intraocular pressure (IOP) have been seen within 60 minutes of intravitreal injections, including Eylea; monitor and manage IOP and optic nerve head perfusion. Take special precautions in patients with poorly controlled glaucoma (do not inject if IOP ≥ 30 mmHg). Potential for immunogenicity as with other therapeutic proteins; patients should report signs or symptoms of intraocular inflammation or hypersensitivity e.g. pain, photophobia or redness. Systemic adverse events including non-ocular haemorrhages and arterial thromboembolic events reported following intravitreal injection of vascular endothelial growth factor (VEGF) inhibitors. Limited data on safety in patients with nAMD and DMO and history of stroke, transient ischaemic attacks or myocardial infarction within last 6 months. Exercise caution when treating such patients. Safety and efficacy of concurrent use in both eyes not studied; potential risk of increased systemic exposure and systemic adverse events. Limited data on concomitant use of Eylea with other anti-VEGF medicinal products (systemic or ocular). Caution in patients with risk factors for development of retinal pigment epithelial tears including large and/or high pigment epithelial retinal detachment. Withhold treatment in patients with: decrease in best-corrected visual acuity of ≥30 letters compared with last assessment; rhegmatogenous retinal detachment or stage 3 or 4 macular holes or with retinal break, subretinal haemorrhage in central fovea or ≥50%, of total lesion area. Do not treat in 28 days prior to or following performed or planned intraocular surgery. Populations with limited data: experience limited in diabetic patients with an HbA1c over 12 % or with proliferative diabetic retinopathy. **Eylea 40 mg/mL only**: limited experience in DMO due to type 1 diabetes. **Eylea 40 mg/mL and Eylea 114.3 mg/mL** have not been studied in patients with active systemic infections, concurrent eye conditions such as retinal detachment or macular hole, or in diabetic patients with uncontrolled hypertension. Consider this lack of information when treating such patients.
**Interactions:** No available data.
**Fertility, pregnancy & lactation:** Do not use in pregnancy unless potential benefit outweighs potential risk to the foetus. Limited data in pregnant women. Animal studies have shown reproductive toxicity. Women of childbearing potential must use effective contraception during treatment and for at least 3 months (**Eylea 40 mg/mL**) or 4 months (**Eylea 114.3 mg/mL**) after last injection. Not recommended during breastfeeding, aflibercept may be excreted in human milk at low levels, effect on infant unknown. No fertility data in humans. Animal studies with high systemic exposure indicate aflibercept can impair male and female fertility.
**Effects on ability to drive and use machines:** Possible temporary visual disturbances. Patients should not drive or use machines until their visual function has recovered sufficiently.
**Undesirable effects**: *Common/very common:* **Eylea 40 mg/mL & 114.3 mg/mL:** cataract, intraocular pressure increased, vitreous floaters, vitreous detachment, vitreous haemorrhage, retinal haemorrhage, visual acuity reduced, eye pain, conjunctival haemorrhage, punctate keratitis, corneal abrasion. **Eylea 114.3 mg/mL:** hypersensitivity. **Eylea 40 mg/mL:** retinal pigment epithelial tear (observed in nAMD studies only) and detachment; retinal degeneration; corneal erosion; blurred vision; injection site pain or haemorrhage; foreign body sensation in eyes; increased lacrimation; eyelid oedema; conjunctival or ocular hyperaemia; *Serious* **Eylea 40 mg/mL & 114.3 mg/mL:** *cf. CI/W&P*: in addition cataract subcapsular and blindness. **Eylea 114.3 mg/mL:** above plus cataract nuclear. **Eylea 40 mg/mL:** above plus isolated cases of severe anaphylactic/anaphylactoid reactions. Theoretical risk of arterial thromboembolic events (ATEs) including stroke and myocardial infarction following intravitreal use of VEGF inhibitors. Across indications, no notable difference in ATEs observed between groups treated with Eylea 114.3 mg/mL and comparator groups treated with Eylea 40 mg/mL. Consult SmPCs in relation to other adverse reactions.

**Overdose:** Monitor intraocular pressure and treat if required.

**Incompatibilities:** Do not mix with other medicinal products.
**Special Precautions for Storage:** Store in a refrigerator (2°C to 8°C). Do not freeze. Keep vial in outer carton and **(for Eylea 40 mg/mL and in Great Britain Eylea 114.3 mg/mL only)** PFS in its blister and in the outer carton to protect from light. Prior to usage, the unopened vial or **(for Eylea 40 mg/mL and in Great Britain Eylea 114.3 mg/mL only)** unopened blister may be stored outside the refrigerator below 25 °C for up to 24 hours.
**Legal Category:** POM.
**Package Quantities & Basic NHS Costs: Eylea 40 mg/mL**: *Single vial + filter needle or PFS pack:* £816.00 **Eylea 114.3 mg/mL**: *Single vial + filter needle or **(in Great Britain only)** PFS pack:* £998.00
**MA Number(s): *Great Britain:*** PLGB 00010/0676, PLGB 00010/0745, PLGB 00010/0754 & PLGB 00010/0758 ***Northern Ireland:*** EU/1/12/797/001-002 & EU/1/12/797/003
**Further information available from:** Bayer plc, 400 South Oak Way, Reading RG2 6AD, United Kingdom. Telephone: 0118 206 3000.
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**Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store.**

**Adverse events should also be reported to Bayer plc. Tel.: 0118 2063500, Email: pvuk@bayer.com**